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Office of Information Resources Management
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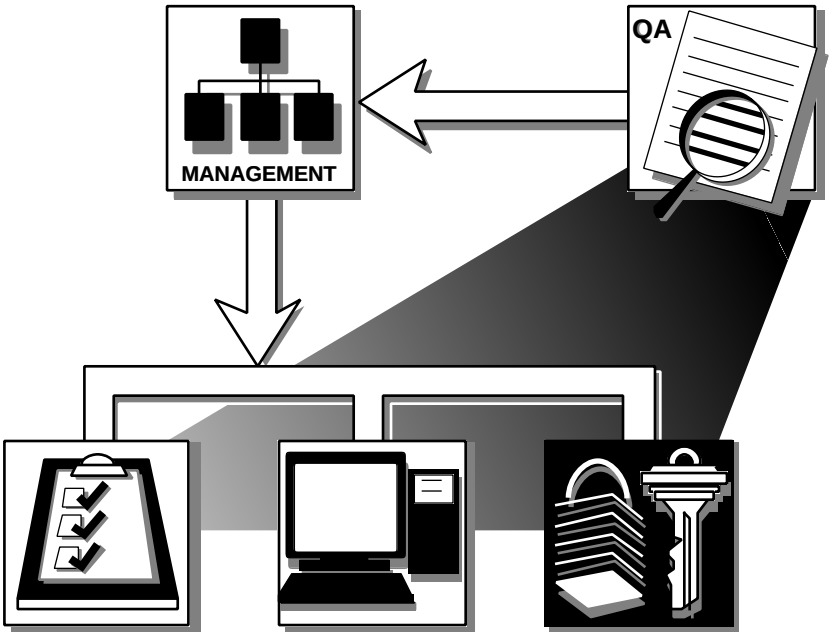
EPA

2185 - Good Automated Laboratory Practices

Principles and Guidance to Regulations For Ensuring Data Integrity In Automated Laboratory Operations

with **Implementation Guidance**

1995 Edition



Good Automated Laboratory Practices

August 10, 1995

Principles and Guidance to
Regulations For Ensuring Data Integrity
In Automated Laboratory Operations

with Implementation Guidance

1995 Edition

Scientific Systems Staff
Office of Information Resources Management
U.S. Environmental Protection Agency
Research Triangle Park, North Carolina 27711

IF a man will begin with certainties, he shall end in doubt; but if he will be content to begin with doubts, he shall end in certainties.

—Francis Bacon

Preface

Most EPA regulatory and research programs have regulations or requirements by contract clause that govern the conduct of laboratory studies. The GALPs *do not* supersede any existing requirements or regulations of EPA's organizations, nor do they augment them. Some of the GALP provisions guide EPA staff and its agents (contractors or grantees) to existing EPA requirements such as the System Life Cycle Management, Chapter 17 of *Information Resources Management Policy Manual*.

The GALPs are developed from essential principles inherent to sustaining challenges to the reliability of data. These include traceability, accountability, standardized procedures, adequate resources, and, importantly, the availability of documentation that supports conformance with these principles. Each GALP provision embraces at least one of these principles.

The intended objective of the GALPs is to provide EPA organizations with a set of benchmarks to examine in light of their needs and established requirements or regulations. If an organization then determines that changes or additions to their own requirements or regulations are needed, it is the responsibility of that organization to amend their requirements or regulations.

The GALPs have been constructed to address realities of 1995. They may be modified over time to reflect changes in U.S. laws such as the congressionally-mandated Computer Security Act, requirements by the Office of Management and Budget, and others. They may also be modified over time to address advances in automated data management technologies.

Executive Summary

This document describes benchmarks, Good Automated Laboratory Practices (GALPs), for assuring the reliability of laboratory data. The GALPs are principles and guidelines to regulations for laboratories that use or are planning to use a wide range of automated data collection and management systems. The GALPs are EPA's response to mounting evidence of corruption, loss, and inappropriate modification of computerized laboratory data by EPA contractors.

The GALPs are a union of Federal regulations, policies, and guidance documents. Several of the GALP provisions are embodied in EPA's Good Laboratory Practice Standards (GLPs). The GLPs are regulations that govern the management and conduct of most nonclinical laboratory studies submitted to EPA's office of Toxic Substances and its Office of Pesticide Programs.

Several GALPs are contained in EPA's Information Resource Management (IRM) policies. These policies prescribe methodologies and practices for using automated data processing hardware and software. The IRM policies are directed to EPA staff and its agents (contractors and grantees) and generally implement broader Federal mandates such as the congressionally-mandated Computer Security Act of 1987, the Office of Management and Budget Circular A-130, and others. Most of these are also specifically required by EPA Acquisition Regulations.

This document is divided into two sections. The first chapter formally establishes the GALPs, describes the purpose they serve, provides background information about studies that led to their development, and explains their scope and applicability. The second chapter provides laboratories with additional explanations of each provision and other relevant information to assist laboratory staff in implementing each applicable provision.

Acknowledgments

This document culminates a six year program by EPA's Office of Information Resources Management (OIRM). Numerous experts in national and international laboratory standards, laboratory automation experts, senior managers and technical staff in government and private companies provided invaluable support.

Mr. Mickey Cline and Dr. Walter Shackelford, both of OIRM, identified the need for the program, ensured that resources were provided, offered many valuable suggestions that helped to focus the program, and provided encouragement when obstacles seemed insurmountable. Without their support this program likely would not be completed.

Ms. Lynn Laubisch's (Durham, NC) contribution to the publication of this document far exceeded her title, "Micro Graphics Specialist." She is responsible for transforming what could have been a dull, monotonous and probably difficult-to-follow publication into a refreshing, easy to read "text book" that enables complex concepts to be easily accessible to a diverse readership. While a cursory review of the document demonstrates her skill in page layout, font selection, and icon and diagram creation, a careful reading of the text is indicative of her oversight in helping to eliminate convoluted sentences and make the text easily readable.

Ms. Stephanie Taublee, Mr. David Brodish both of Research Triangle Institute (RTI), and Ms. Terrie Baker, formerly of RTI, deserve most of the credit for the areas of quality assurance (QA) the GALPs embrace and explain. Their professional QA experience, dedication, determination and commitment to doing the right thing on time, and their ability to examine highly charged and sensitive issues from several angles were essential.

Mr. Keith McLaurin of Technology Planning and Management Corporation (TPMC), Mr. Don Weyel, formerly of TPMC, and Mr. Bill Hampton, a Consultant to TPMC, instilled a wealth of the discipline of Computer Science to the GALPs. Their knowledge and experience in automated system design and development, computing and

communication technologies, and the evolving specialized area of computer security enabled issues related to current computing environments, system life cycle and a myriad of intricate factors affecting computing security to be thoroughly and accurately explained in the document.

Mr. Dexter Goldman of Goldman and Associates enthusiastically supported this program from its inception. His extensive experience in EPA's *Good Laboratory Practice Standards* is reflected in many areas of the document. His critical review of earlier drafts was essential. He identified and recommended numerous changes not noted by other reviewers that, though subtle, had profound impact.

Dr. Sandy Weinberg of Weinberg, Sax and Spelton Associates deserves much of the credit for getting this program started in the right direction. He afforded the program with an unparalleled wealth of experience in assisting laboratories in complying with national laboratory standards, auditing laboratory operations, and translating national and international laboratory guidelines into laboratory operating standards.

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